**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

**A. 510(k) Number:** k040974

**B. Purpose For Submission:**

Premarket Notification 510(k) for GenChem, Inc. intentions to manufacture and market the GenChem Glucose Reagent Kit.

**C. Analyte:** Glucose

**D. Type of Test:**

Quantitative, Photometric End-Point

**E. Applicant:** GenChem, Inc.

**F. Proprietary and Established Names:**

GenChem, Inc, Glucose Reagent

**G. Regulatory Information:**

Regulation section:

1. Regulation section:

21 CFR §862.1345 - Glucose Test System

2. Classification:

Class II

3. Product Code:

CGA

4. Panel:

75 (Chemistry)

**H. Intended use(s):**

1. Intended use(s)

The GenChem Glucose Oxidase Reagent is used for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid on the Beckman SYNCHRON CX3 System to aid in the diagnosis of diabetes, liver disease and certain endocrine disorders.

2. Indication(s) for use:

The GenChem Glucose Oxidase Reagent is used for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid on the Beckman SYNCHRON CX3 System to aid in the diagnosis of diabetes, liver disease and certain endocrine disorders.

3. Special condition for use statement(s): For Prescription Use.

4. Special instrument Requirements: Beckman CX3 System.

**I. Device Description:**

The device is a solution containing sufficient Glucose Oxidase, surfactants and other ingredients necessary for optimum system operation on the Beckman SYNCHRON CX3 System.

**J. Substantial Equivalence Information:**

GenChem claims substantial equivalence to the Beckman GLUCOSE Reagent for the CX3.

1. Predicate device name(s): Beckman Bun reagent for the CX3

2. Predicate K number(s): (k761060)

3. Comparison with Predicate:

| Device Name | GenChem Glucose Reagent Kit | Predicate Device Beckman Glucose Oxidase Reagent |
|---|---|---|
| 510(k) Number | (k040974) | (k761060) |
| Chemical Principle | Oxygen rate method | Oxygen rate method |
| Intended Use | For the quantitative determination of glucose in serum, plasma, urine, or CSF | For the quantitative determination of glucose in serum, plasma, urine, or CSF |
| Format | Liquid, ready to use | Liquid, ready to use |
| Composition | Glucose Oxidase, buffer and non-reactive chemicals | Glucose Oxidase, buffer and non-reactive chemicals |
| Linearity | 0-800 mg/dL | 0-450 mg/dL |
| Storage | 2-8 °C | 2-8 °C |

**K. Standard/Guidance Document Referenced (if applicable):**

Within-Day and Day-to-Day precision was determined according to NCCLS EP5-A.
Linearity was performed according to NCCLS EP6-A Guideline.
Analytical specificity Determined according to NCCLS EP7-A.

**L. Test Principle:**

This test utilizes a enzymatic method. Early methods for glucose were based on the binding of o-toluidine dye and on the reduction of either alkaline ferricyanide or cupric ions. These early methods have been replaced by enzymatic procedures largely due to the improvements in both specificity and precision. In 1969, Kadish introduced an enzymatic method that measured glucose by means of a modified polarographic oxygen sensor. This reagent is an adaptation of that methodology.

**Principles of Procedure:**

$$\text{Glucose} + O_2 \xrightarrow{GO,\ H_2O} \text{Gluconic Acid} + H_2O_2$$

Glucose from the sample reacts with the oxygen in the reagent in the presence of glucose oxidase (GO). The oxygen, which is consumed in direct proportion to the glucose, is monitored using an oxygen electrode, and the rate of its depletion is a measure of the amount of glucose in the sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
    *a. Precision/Reproducibility:*

Within-Day and Day-to-Day precision was determined according to NCCLS EP5-A. Results are summarized below:
Control sera and spiked urine pools were each assayed in triplicate, two times per day over 10 days on a SYNCHRON CX3 System.

| | | Within Run | | | Total | |
|---|---|---|---|---|---|---|
| **Sample** | **n** | **mean** | **SD** | **%CV** | **SD** | **%CV** |
| Serum1 | 60 | 51 | 0.7 | 1.4 | 1.1 | 2.1 |
| Serum 2 | 60 | 220 | 1.3 | 0.6 | 2.3 | 1.1 |
| Serum 3 | 60 | 387 | 2.3 | 0.6 | 5.1 | 1.3 |
| CSF 1 | 60 | 57 | 0.7 | 1.2 | 1.4 | 2.4 |
| CSF 2 | 60 | 33 | 0.6 | 1. | 1.4 | 4.1 |
| Urine 1 | 59 | 24 | 0.7 | 2.9 | 1.4 | 5.8 |
| Urine 2 | 60 | 315 | 3.2 | 1. | 5.1 | 1.6 |

Two additional control sera were spiked with glucose and assayed as described above using ORDAC sample dilution.

Precision of ORDAC Glucose Recoveries (mg/dL)

| | | Within Run | | | Total | |
|---|---|---|---|---|---|---|
| Sample | n | mean | SD | %CV | SD | %CV |
| Serum 1 | 60 | 557 | 8.1 | 1.5 | 10.0 | 1.8 |
| Serum 2 | 60 | 770 | 7.1 | 0.9 | 11.8 | 1.5 |

*b. Linearity/assay reportable range:*

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards ranging from 0 to 800 mg/dL were analyzed in triplicate on the Beckman CX3 and the results analyzed by the Least Squares method. The results gave a slope of 1.012 with an intercept of 0.1.97, a standard error of estimate of 6.83 and $r^2$ = 1.000. Samples exceeding these limits should be diluted with normal saline and reanalyzed. Multiply the result by the appropriate dilution factor.

| Specimens | range | Conventional units | SI Units |
|---|---|---|---|
| All | Normal | 5 to 450 mg/dL | 0.3 to 25 mmol/L |
| All | ORDAC | 450 to 900 mg/dL | 25 to 50 mmol/L |

*c. Traceability (controls, calibrators, or method):*

Beckman Calibration Standards 1 and 2 for the CX3 System

*d. Detection limit:*

The sensitivity of this method was investigated by assaying serum first with a known concentration and then diluting the sample until the minimum result obtained and then run in replicates of 10 on the SYNCHRON CX3 System. Under the conditions described the limit of detection for this method was found to be 5.0 mg/dL.

| **Analyte** | **Limit of Detection** |
|---|---|
| GLUCOSE | 5.0 mg/dL |

*e. Analytical specificity:*

Determined according to NCCLS EP7-A. Hemoglobin levels up to 500 mg/dL, Bilirubin levels up to 20 mg/dL, and Lipemia levels up to 1800 mg/dL were tested and did not show any adverse effect on a stock sample with a glucose level of 96 mg/dL. Stock solutions of the substance to be tested were prepared at 20x concentrations and 0.5 ml of this stock was placed in a 10 ml volumetric flask and made up to volume with the base pool. The control stock was prepared similarly but with water as the diluent. Heparin, Lithium Heparin, Ammonium Heparin, and EDTA, sodium fluoride and potassium oxalate are acceptable anticoagulants.

*f. Assay cut-off:*

Not applicable for this type of device.

2. Comparison studies:

*a. Method comparison with predicate device:*

Serum, plasma and CSF specimens, and urine specimens spiked with glucose were collected from adult patients and assayed using GenChem and Beckman glucose reagents on a SYNCHRON CX3 System. Results were compared by least squares linear regression and the following statistics were obtained.

| **VALUE** | **SERUM** | **PLASMA** | **URINE** | **CSF** |
|---|---|---|---|---|
| | | | | |
| Intercept | -1.2 | 1.0 | -2.1 | 1.0 |
| | | | | |
| Slope | 1.011 | 1.000 | 1.012 | 0.973 |
| | | | | |
| $R^2$ Value | 0.999 | 0.999 | 0.999 | 0.999 |
| | | | | |
| N | 79 | 80 | 81 | 45 |
| | | | | |
| Range (mg/dL) | 29 -341 | 30 – 350 | 1 – 359 | 3 – 186 |

*b.* Matrix Comparison

See above method comparison studies.

3. Clinical studies:

*a. Clinical sensitivity:*

Clinical studies are not typically submitted for this device type.

*b. Clinical specificity:*

Clinical studies are not typically submitted for this device type.

*c. Other clinical supportive data (when a and b are not applicable):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values for glucose are listed below. Use these ranges only as guides. Each laboratory should establish its own reference ranges.

| | Reference Ranges[1] | |
|---|---|---|
| Specimens | Conventional Units | SI Units |
| Serum/Plasma | 70 - 105 mg/dL | 3.89 - 5.83 mmol/L |
| Urine (Random) | 1 - 15 mg/dL | 0.1 - 0.8 mmol/L |
| Urine (Timed) | < 0.5 g/day | < 2.8 mmol/day |
| CSF | 40 - 70 mg/dL | 2.22 - 3.89 mmol/L |

1. Burtis, C.A., Ashwood, E.R. (eds.). Tietz Textbook of Clinical Chemistry. W.B. Saunders Company. Philadelphia, PA. (1994).

**N. Conclusion:**

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.